



Rhode Island Department of Health

NOTICE OF PUBLIC HEARING

The Director of the Rhode Island Department of Health has under consideration the proposed *Rules and Regulations Pertaining to the Utilization of Unused Prescription Drugs (R23-25.4-DRUGS)*. These are proposed new regulations promulgated in accordance with Public Law 05-179 enacted by the Rhode Island General Assembly on July 6, 2005.

Notice is hereby given in accordance with the provisions of Chapter 42-35 of the Rhode Island General Laws, as amended, that the Director will hold a public hearing on the above mentioned matter, in the **AUDITORIUM** of the Cannon Building (on the lower level), Rhode Island Department of Health, 3 Capitol Hill, Providence, Rhode Island on **THURSDAY, OCTOBER 20, 2005 at 10:00 A.M.** at which time and place all persons interested therein will be heard. The seating capacity of the Cannon Building room will be enforced and therefore the number of persons participating in the hearing may be limited at any given time by the hearing officer, in order to comply with safety and fire codes.

In the development of the rules and regulations, consideration was given to the following: (1) alternative approaches; (2) overlap or duplication with other statutory and regulatory provisions; and (3) significant economic impact on small business, as defined in Chapter 42-35 of the Rhode Island General Laws, as amended, which may result from the regulations. No alternative approach or duplication or overlap was identified based upon available information. The health, safety, and welfare of the public precludes any economic impact that may be incurred as a result of these regulations.

For the sake of accuracy, it is requested that statements to be made relative to any aspect of the regulations, including alternative approaches, overlap, or significant economic impact, be submitted in writing at the time of the hearing or mailed prior to the hearing date to: David R. Gifford, M.D., M.P.H., Director, Rhode Island Department of Health, #401 Cannon Building, 3 Capitol Hill, Providence, Rhode Island 02908-5097.

Copies of the regulations are available for public inspection in the Cannon Building, Room #404, Rhode Island Department of Health, 3 Capitol Hill, Providence, Rhode Island, on the Department's website: www.health.ri.gov/hsr/regulations/index.php or the Secretary of State's website: www.rules.state.ri.us/rules/, by calling 401-222-1039, or by e-mailing: LizS@doh.state.ri.us.

The Cannon Building is accessible to the handicapped. Individuals requesting interpreter services for the hearing impaired must notify the Office of Health Services Regulation at 401-222-1600 (Hearing/speech impaired, dial 711) at least 72 hours prior to the hearing.

Signed this 9th day of September 2005

David R. Gifford, M.D., M.P.H. , Director of Health

RULES AND REGULATIONS
PERTAINING TO THE
UTILIZATION OF UNUSED
PRESCRIPTION DRUGS

(R23-25.4-DRUGS)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

SEPTEMBER 2005 (Proposed)

COMPILER'S NOTE:
Statutory language noted in italics.

INTRODUCTION

These rules and regulations are promulgated under the authority of Chapters 23-25.4 and 42-35 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting prevailing standards pertaining to a program for the utilization of unused prescription drugs in Rhode Island.

The General Assembly has determined that the high cost of prescription drugs is a burden on the uninsured who may forego the drugs they need or take only partial doses which can ultimately increase health costs. The General Assembly has also determined that many nursing facilities and assisted living residences destroy quantities of unused but viable prescription medications when residents pass away or when medications otherwise are no longer needed by the resident. In an effort to improve the quality, efficiency and utilization of the state's health care system, the General Assembly hereby establishes a voluntary statewide pilot program allowing nursing facilities and assisted living residences to transfer from their facilities unused prescription drugs to authorized participating pharmacies for distribution to medically indigent Rhode Island residents.

Pursuant to the provisions of section 42-35-3(c) of the General Laws of Rhode Island, as amended, consideration was given to: (1) alternative approaches to the regulations; (2) duplication or overlap with other state regulations; and (3) significant economic impact placed on small business as defined in Chapter 42- 35 of the General Laws as a result of the amended regulations. No alternative approach, overlap or duplication nor any significant economic impact was identified; consequently the regulations are adopted in the best interest of the health, safety and welfare of the public.

TABLE OF CONTENTS

	<i>Page</i>
1.0 Definitions	1
2.0 General Program Requirements	3
3.0 Criteria for Accepting/Donating Unused Prescriptions into the Program	4
4.0 Role of the Program Pharmacist at the Nursing Facility or Assisted Living Residence	5
5.0 Requirements for Charitable Clinic Pharmacy	6
6.0 Formulary	7
7.0 Recalls and Destruction of Drugs	7
8.0 Labeling	7
9.0 Liability	8
10.0 Severability	8
References	9

Section 1.0 **Definitions**

Wherever used in these rules and regulations, the following terms shall be construed as follows:

- 1.1 **"The Act"** means Chapter 23-25.4 of the Rhode Island General Laws, as amended, entitled, "The Utilization of Unused Prescription Drugs Act."
- 1.2 **"Assisted living residence licensed at the M-1 level"** means a publicly or privately operated residence that provides directly or indirectly by means of contracts or arrangements personal assistance to meet the resident's changing needs and preferences, including central storage and/or administration of medications, lodging, and meals to two (2) or more adults who are unrelated to the licensee or administrator, excluding however, any privately operated establishment or facility licensed pursuant to Chapter 23-17 of the General Laws of Rhode Island, as amended, and those facilities licensed by or under the jurisdiction of the Department of Mental Health, Retardation and Hospitals, the Department of Children, Youth, and Families, or any other state agency. Assisted living residences include sheltered care homes, and board and care residences, or any other entity by any other name providing the above services which meet the definition of assisted living residence.
- 1.3 **"Blister packages"** means multi-dose containers of a specific medication repackaged by the pharmacy in accordance with section 13.7 of the regulations promulgated under Chapter 19.1 of Title 5 and intended for a specific patient.
- 1.4 **"Charitable clinic"** means an organized ambulatory care facility licensed pursuant to Chapter 17 of Title 23 organized as a nonprofit corporation pursuant to section 7-6-2 of the Rhode Island General Laws, as amended, that:
 - 1.4.1 *Holds a valid exemption from federal income taxation issued pursuant to Section 501(a) of the Internal Revenue Code (26 U.S.C., Section 501(1));*
 - 1.4.2 *Has a licensed outpatient pharmacy located at the organized ambulatory care facility or a contract with a retail pharmacy to participate in the program established under the Act.*
- 1.5 **"Controlled substance"** means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of Chapter 21-28 of the Rhode Island General Laws, as amended.
- 1.6 **"Department"** means the Rhode Island Department of Health.
- 1.7 **"Director"** means the Director of the Rhode Island Department of Health.
- 1.8 **"Dispense" or "dispensing"** means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

- 1.9 ***"Health care prescriber"** means any of the following persons licensed and authorized to prescribe drugs or to provide medical, dental, or other health-related diagnoses, care or treatment within the scope of their professional license:*
- 1.9.1 *A physician holding a current license to practice medicine pursuant to Chapter 37 of Title 5;*
- 1.9.2 *A certified registered nurse practitioner licensed pursuant to Chapter 34 of Title 5;*
- 1.9.3 *A physician assistant licensed pursuant to Chapter 54 of Title 5;*
- 1.9.4 *A dentist licensed pursuant to Chapter 31.1 of Title 5;*
- 1.9.5 *An optometrist licensed pursuant to Chapter 35 of Title 5; and*
- 1.9.6 *A nurse – midwife licensed pursuant to Chapter 13 of Title 23; and*
- 1.9.7 *A psychiatric and mental health clinical nurse specialist licensed pursuant to Chapter 34 of Title 5.*
- 1.10 ***"Manifest"** means an invoice used to list drugs being transferred or destroyed.*
- 1.11 ***"Medically indigent"** means a person eligible to receive Medicaid or Medicare or a person who has no health insurance and who otherwise lacks reasonable means to purchase prescribed drugs.*
- 1.12 ***"Nursing facility"** means a place, however named, or an identifiable unit or distinct part thereof that provides 24 hour in-resident nursing, therapeutic, restorative or preventive and supportive nursing care services for two (2) or more residents unrelated by blood or marriage whose condition requires continuous nursing care and supervision.*
- 1.13 ***"Pharmacist"** means an individual licensed to engage in the practice of pharmacy in this state pursuant to section 5-19.1-14 of the Rhode Island General Laws, as amended.*
- 1.14 ***"Pharmacy"** means that portion or part of a premises where prescriptions are compounded and dispensed, including that portion utilized for the storage of prescription or legend drugs.*
- 1.15 ***"Prescription drug"** means a drug that may be dispensed only upon prescription by a health care prescriber authorized by his or her licensing authority and as defined in section 5-19.1 of the Rhode Island General Laws, as amended.*
- 1.16 ***"Unit-dose container"** is one that is designed to hold a quantity of a drug intended for use as a single dose and used promptly after the container is opened. The immediate container, and/or the outer container or protective packaging shall be designed to show evidence of any tampering with the contents. Each individual container shall be fully identifiable containing a single dose of a single entity and shall protect the integrity of the dosage form. Labeling shall be in accordance with USP standards compendia and federal and state law and shall include the identity, quantity, and strength of the product, name of the manufacturer, and lot number and expiration date of the article.*

Section 2.0 **General Program Requirements**

- 2.1 *The Department and the Board of Pharmacy shall jointly develop and implement a pilot program consistent with public health and safety through which unused prescription drugs, other than prescription drugs defined as controlled substances in section 21-28-1.02, may be transferred from nursing facilities or assisted living residences that centrally store prescription drugs and are licensed at the M1 licensure level by the Department to charitable clinics for the purpose of re-dispensing the medication to Rhode Island residents who are medically indigent.*
- 2.2 *The pilot program shall remain in effect until January 1, 2007.*
- 2.3 *Notwithstanding any other provision in these rules and regulations to the contrary, any dispenser of donated products shall not submit a claim or otherwise seek reimbursement from any public and/or private third party payer for donated drugs dispensed to any patient through the drug reuse program and no public and/or private third party payers shall be required to provide reimbursement for donated drugs dispensed to any patient through the drug reuse program.*

Participation in the Program

- 2.4 *Participation in the program established in the Act by individual residents of any assisted living residence or nursing facility, pharmacies, nursing facilities, assisted living residences, or charitable clinics shall be voluntary.*
- 2.5 *Nothing in the Act shall require any resident of any assisted living residence or nursing facility, pharmacy, pharmacists, or charitable clinic to participate in the program.*
- 2.6 *A pharmacy operating in conjunction with a charitable clinic may re-dispense prescription drugs donated pursuant to the Act to persons who are medically indigent residents of Rhode Island.*
- 2.7 *A pharmacy operating in conjunction with a charitable clinic wherein both meet the eligibility requirements established and authorized by the Act and Chapter 5-19.1 of the Rhode Island General Laws, as amended, and that accepts donated prescription drugs shall:*
 - 2.7.1 *Comply with all applicable federal and state laws relating to the storage, distribution, and dispensing of prescription drugs;*
 - 2.7.2 *Inspect all prescription drugs prior to re-dispensing the prescription drugs to determine that such drugs are not adulterated; and*
 - 2.7.3 *Re-dispense prescription drugs only pursuant to a valid prescription issued by a health care prescriber.*
- 2.8 *Prescription drugs donated pursuant to the Act shall not be resold.*
- 2.9 *A resident of a nursing facility or assisted living residence, or the representative or guardian of a resident may donate unused prescription medications, other than prescription*

drugs defined as controlled dangerous substances, to charitable clinics for dispensing to medically indigent persons.

- 2.9.1 A resident or the legal guardian of the resident shall authorize in writing the donation of the resident's unused prescription drug(s).

Section 3.0 *Criteria for Accepting/Donating Unused Prescriptions into the Program*

- 3.1 *The following criteria shall be used in soliciting and accepting unused prescription drugs for use pursuant to the Act:*

- 3.1.1 *Nursing facilities and assisted living residences that have entered into an agreement to participate with a charitable clinic shall document residents' participation in the program with a written statement that their excess and otherwise eligible unused prescription drugs shall be donated to a charitable clinic for the purpose of re-dispensing to medically indigent persons.*
- 3.1.2 *Participation in this program by residents of participating nursing facilities and assisted living residences shall be strictly voluntary.*
- 3.1.3 *Only prescription drugs in their original sealed multi-dose blister packages, unit dose containers or perforated blister packages shall be accepted and re-dispensed.*
- 3.1.4 *Expired or beyond use date prescription drugs shall not be accepted.*
- 3.1.5 *A prescription drug shall not be accepted or re-dispensed if the pharmacist accepting or re-dispensing the drug, in his or her judgment, has reason to believe that the drug is adulterated, mislabeled, or has been improperly stored.*
- 3.1.6 *No controlled substances shall be accepted. and*
- 3.1.7 *Subject to the limitation specified in this section, unused prescription drugs dispensed for purposes of a medical assistance program may be accepted and re-dispensed pursuant to the Act.*

Eligibility to Donate Prescription Drugs

- 3.2 Residents of nursing facilities and assisted living residences (M-1 level) licensed, and in good standing, with the Department may donate eligible unused prescription drugs.
- 3.3 Licensed health care personnel shall have kept control of the unused prescription drugs in sanitary and secure conditions. Only those drugs that have been under the control of licensed health care personnel in sanitary and secure conditions shall be accepted for donation.
- 3.4 Each nursing facility and assisted living residence (M-1 level) seeking to participate in the program shall have a program pharmacist who shall be responsible for the donation and transfer of the prescription drugs to the charitable clinic pharmacist.

Section 4.0 ***Role of the Program Pharmacist at the Nursing Facility or Assisted Living Residence***

- 4.1 A program pharmacist for the nursing facility or assisted living residence eligible to donate unused prescription drugs shall be responsible for the following:
- 4.1.1 Determine quality and suitability of the unused prescription drugs for reuse by ensuring that:
 - The drugs have been kept under the control of licensed health care personnel;
 - The drugs have been stored properly (with respect to heat, cold, moisture, etc.);
 - The drugs can be identified; and
 - The drugs are not adulterated, mutilated, or otherwise compromised.
 - 4.1.2 Determine that the expiration date exceeds 45 days to allow time for re-distribution,
 - 4.1.3 Properly complete a manifest that includes no less than the following information:
 - Names of consulting pharmacist(s);
 - Names of facility/residence administrator, director of nursing, or designee;
 - The name of the facility/residence;
 - The name of the receiving pharmacy;
 - Name and strength of the eligible prescription drug;
 - Expiration date of the eligible prescription drug; and
 - Number of tablets or capsules or volume, if liquid or injectable.
 - 4.1.4 Ensure that controlled substances are not redistributed and are handled in accordance with all applicable federal and state laws and regulations.
 - 4.1.5 Ensure that the charitable clinic pharmacy is eligible to receive unused prescription medications under the Act and the rules and regulations contained herein.
 - 4.1.6 Notify the charitable clinic pharmacy when the drugs are ready to be transported.
 - 4.1.7 Determine, in conjunction with facility/residence designee, that the resident has authorized the donation of the drugs in writing.
 - 4.1.8 Ensure that the name of the resident, pharmacy and directions for use on the label have been redacted with black ink or removed before sending to the charitable clinic pharmacy, in order to safeguard the confidentiality of the resident.
- 4.2 A copy of the manifest required in section 4.1.3 herein shall be provided to the charitable clinic pharmacist and a copy shall be maintained by the nursing facility or assisted living residence for a minimum of two (2) years.
- 4.3 Written notification of participation in the program shall be completed by the program pharmacist on behalf of the facility/residence and shall be submitted to the Board.

Section 5.0 *Requirements for Charitable Clinic Pharmacy*

- 5.1 Charitable clinic pharmacies dispensing unused prescription drugs shall comply with the following requirements:
 - 5.1.1 Maintain a current drug identification book, or have such computer program/online service of same;
 - 5.1.2 Dispense unused prescription drugs only upon the valid prescription of a Rhode Island licensed health care prescriber;
 - 5.1.3 Properly label all dispensed donated prescription drugs;
 - 5.1.4 Comply with all federal and state laws and regulations regarding storage and distribution of prescription drugs;
 - 5.1.5 Inspect all prescription drugs prior to dispensing to determine that the donated drugs meet all federal and state requirements for product integrity.
- 5.2 The transportation of the unused drugs shall be the responsibility of the eligible charitable clinic pharmacy. Such charitable clinic pharmacy shall pick up all donated drugs in an expedient manner.
- 5.3 Prior to beginning or terminating participation in the program, the charitable clinic pharmacy shall send written notice to the Board.

Role of the Pharmacist-in-Charge

- 5.4 The pharmacist in charge at the charitable clinic pharmacy shall be responsible for the following:
 - 5.4.1 Coordinate retrieval of donated unused prescription drugs from nursing homes and assisted living residences. Such retrieval shall be completed in an expedient manner.
 - 5.4.2 Check unused prescription drugs against the manifest and resolve any discrepancies;
 - 5.4.3 Store and secure the unused prescription drugs as required under state and federal law and regulations;
 - 5.4.4 Check the unused prescription drugs for adulteration;
 - 5.4.5 Ensure that expired, adulterated, lost-identity drugs are not dispensed. Ensure that such unacceptable drugs are not put back into dispensing stock.
 - 5.4.6 Ensure safety in drug recalls;
 - 5.4.7 Ensure destruction of expired, adulterated, and/or recalled unused prescription drugs.

Section 6.0 ***Formulary***

- 6.1 The formulary of unused prescription drugs shall include all FDA approved prescription drugs, but shall exclude any controlled substances (schedules I—V) and except as otherwise restricted herein.
- 6.2 Compounded drugs shall not be eligible for redistribution.
- 6.3 In order to be considered part of the formulary of unused prescription drugs, the following drug criteria shall be met:
 - 6.3.1 Drugs shall be in original sealed unit dose packaging or unused injectables;
 - 6.3.2 Drug packaging shall be intact and unopened;
 - 6.3.3 Drugs shall not be expired;
 - 6.3.4 Drug identity shall be known (i.e., no unknown drugs);
 - 6.3.5 Drugs shall not be adulterated; and
 - 6.3.6 Drugs shall not have been held outside of a licensed health care personnel's control where sanitation and security cannot be ensured.

Section 7.0 ***Recalls and Destruction of Drugs***

Drug Recalls

- 7.1 If a drug is recalled and the charitable clinic pharmacy does not have the lot number(s) on the donated drug label to differentiate between the recalled and non-recalled drugs, all such donated recalled drugs shall be destroyed.

Drug Destruction

- 7.2 A manifest shall be made of unused prescription drugs that are expired, adulterated and/or recalled that are to be destroyed. Following the destruction of the drugs, said manifest shall be signed by the pharmacist-in-charge and a witness verifying such destruction.
- 7.3 The drug destruction manifest shall be kept on file by the charitable clinic pharmacy for two (2) years following destruction of the drugs.

Section 8.0 ***Labeling***

- 8.1 All previous patient or pharmacy labeling on an unused prescription drug shall be redacted or removed by the charitable clinic pharmacy.
- 8.2 Dispensed prescription drugs for a medically indigent patient shall clearly indicate the final dispensing pharmacy and the current patient information to ensure clarity for receiving patient.

- 8.3 All dispensed prescription drugs shall be properly labeled in accordance with the rules and regulations of reference 1 herein, Chapter 21-31 of the Rhode Island General Laws, as amended, and any other applicable federal and state laws and regulations.
- 8.4 The expiration date shall be brought forward to the filled prescription if only one expiration date is used in the filling of the prescription. If multiple packages of unused prescription drugs are used to fill a single prescription with varying expiration dates, the shortest expiration date shall be used for the dispensed prescription drug.

Section 9.0 ***Liability***

- 9.1 *For matters related only to the lawful donation, acceptance, or re-dispensing of prescription drugs under the Act, the following persons and entities, in compliance with the criteria set forth in the Act, in the absence of bad faith shall not be subject to criminal or civil liability for injury, death, or loss to person or property, or professional disciplinary action:*
- 9.1.1 *The Board of Pharmacy;*
- 9.1.2 *Any resident of a nursing facility or assisted living residence who agrees to donate unused prescription drugs, or his/her next of kin or legal guardian or estate;*
- 9.1.3 *Any charitable clinic, governmental entity, nursing facility, or assisted living residence who participates in the program for the reuse of prescription drugs pursuant to the Act;*
- 9.1.4 *Any charitable clinic, health care prescriber or pharmacy that accepts or re-dispenses prescription drugs pursuant to the Act; and*
- 9.1.5 *Any pharmacy or pharmacist operating in conjunction with a charitable clinic, or other state-contracted pharmacy that employs a health care professional who accepts or can legally dispense prescription drugs pursuant to the Act.*
- 9.2 *For matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the prescription drug manufacturer that is donated by any entity pursuant to the Act, a prescription drug manufacturer shall not, in the absence of bad faith be subject to criminal or civil liability for injury, death, or loss to person or property including, but not limited to, liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.*

Section 10.0 ***Severability***

- 10.1 If any provision of these rules and regulations or the application thereof to any person or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of the rules and regulations which can be given effect, and to this end the provisions of the rules and regulations are declared to be severable.

REFERENCES

1. *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors (R5-19.1-PHAR)*, Rhode Island Department of Health, July 2005 and subsequent amendments thereto. Available online: http://www.rules.state.ri.us/rules/released/pdf/DOH/DOH_3596.pdf
2. Chapter 21-31 of the Rhode Island General Laws, as amended, “Rhode Island Food, Drugs, and Cosmetics Act.” Available online: <http://www.rilin.state.ri.us/Statutes/TITLE21/21-31/INDEX.HTM>